EXHIBIT 1

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EXHIBIT 1

THE VIDEOGRAPHER: Good morning.
We are now on the record. My name is Katrina McCray, videographer for Byers & Anderson Court Reporters located at 600 University Street, Suite 2300 Seattle, Washington, 98101.
Today is November 12th, 2001, and it is now 8:59 a.m. This is the videotaped deposition of Dr. David Persing being taken in the case of Gen-Probe, Incorporated, versus Vysis, Incorporated, Cause No. 99CV2668 H.
Today's deposition is being held at the law offices of Coolly Godward in Kirkland, Washington.
Will the attorneys present please introduce themselves for the record.
MR. BOWEN: William Bowen, Gen-Probe, Incorporated, for plaintiff Gen-Probe, Incorporated.
MR. LIPSEY: Charles Lipsey, Finnegan, Henderson, Farabow, Garrett, & Dunner, for the defendant Vysis and for the witness, Dr. Persing.
THE VIDEOGRAPHER: The court reporter today is Barbara Hayden. You may swear in the witness and proceed at this time.

DAVID H. PERSING, M.D., Ph.D., having been first duly sworn by the Notary, deposed and testified as follows:

MR. LIPSEY: Mr. Bowen, before we get started, Gen-Probe served upon Dr. Persing on Friday a subpoena seeking production of documents this morning. Dr. Persing and Vysis object to the scope of the subpoena as being unduly broad and encompassing material that's burdensome to collect, that's irrelevant and immaterial and not reasonably calculated to lead to the discovery of admissible evidence. We made an effort to locate documents reflecting the materials that Dr. Persing had been sent or sent or considered in formulating his opinions, and were able to gather a stack of materials about two feet high which we've given you here this morning, but would otherwise object to responding to the subpoena.

MR. BOWEN: I'd like to mark as --

Q (By Mr. Bowen) Would you please state your name.

A David Persing.

Q Dr. Persing, I'd like you to look at what we will mark as Exhibit 1 to your deposition, a subpoena in the case of Gen-Probe versus Vysis. Have you seen Exhibit 1

A (Witness reviews document.) I really can't comment any further beyond what I've already said.
Q Can you tell me what your understanding is of the term specific amplification?
A Specific amplification is a process whereby nucleic acids are amplified from a target template using a combination of sequence specific oligonucleotide primers, and during the amplification process both target specific and nontarget specific templates are co-amplified in the reaction.
But in a specific amplification process, what we call specific in the field of molecular diagnostics, there is a general enrichment for the target nucleotide sequence in favor of nonspecific amplification products. And so there tends to be an increase in the number of needles in the needle in the haystack analogy where you have a needle within a large haystack and trying to find the needle. A specific amplification process would generate more needles than hay straws, but there are some hay straws that get generated in the process as well.
Nonspecific amplification processes may also use oligonucleotides within the amplification mixture, some of which are sequence specific just by virtue of their random sequence composition. And those oligonucleotides

can initiate a sequence specific process, but in general the accumulation of target, target within -- using the needle in a haystack analogy accumulation of the number of needles is in proportion to the rest of the haystack. And so there isn't as much if any, general enrichment for needles within the haystack.

So that's why target capture is useful, because target capture can enrich for the needles prior to amplification, and thus one can use a nonspecific as well as a specific amplification process on the captured needles, and the end result is the same. And in that context, the specific and nonspecific amplification processes are functioning equivalently.

Q I believe in a portion of your answer where you were discussing specific amplification you said with respect to specific amplification that the process in the field results in general enrichment in favor of nonspecific amplification products?

A If I said that I was mistaken. I said that both specific and nonspecific amplification products are generated during even what we call a specific amplification reaction and that in many cases the nonspecific amplification products can outnumber the specific amplification products, but there's general proportional enrichment for the target specific

sequences within what we call a specific amplification process relative to the nonspecific amplification products.

Q Towards the end of your answer you made a statement about the benefit of target capture in connection with both specific and nonspecific amplification. Considering specific amplification and nonspecific amplification without such a target capture step, is nonspecific amplification substantially different from specific amplification in your understanding?

MR. LIPSEY: Object to the form.

A Well, as I've stated in my expert report for the purposes of this amplification when working with purified template, both specific and nonspecific amplification processes are capable of generating the same net result.

MR. BOWEN: Objection. Move to strike, not responsive.

Q (By Mr. Bowen) I'm asking you now, though, to consider the methods without target capture. And I know that you in your opinion have expressed views considering target capture as a preliminary step, but I'd like to explore with you, which I'm entitled to do, your views of the methods without such a step. Vysis and Gen-Probe may argue what the legal relevance of those questions are.

But I'd like to explore and get your views on the methods without a preliminary target capture step. So my question to you is, if one was to practice nonspecific amplification without a target capture step, would it be substantially different than specific amplification?

MR. LIPSEY: Object to the form, lack of foundation, beyond the scope of his report.

A I don't think I can really comment on that based on my involvement with this case and the material that I've been exposed to. I think I might be stepping outside of my bounds if I comment on that.

Q (By Mr. Bowen) So you don't have an opinion on whether or not nonspecific amplification considered without a target capture step is substantially different than specific amplification?

A I think the target capture step is so -- and a target enrichment step, whether it's target capture or any other method, is so central to those amplification techniques that I don't think it's worthy of consideration outside of the sample preparation process.

Q Do you have any understanding that PCR is practiced without a target capture step?

A Yes, I'm aware that that is one -- one way of performing PCR.

understanding is that for some sample types, TMA is a viable diagnostic method without a target capture step?
A In sample types that already have a natural state of enrichment of the target sequence, I think both TMA and PCR perform better. The diagnostic result is more accurate because of the lack of competing nucleic acids within the sample.
Q The FDA has approved diagnostic kits using PCR and TMA without a target capture step; is --
A Right.
Q -- that your understanding?
A Yes.
Q Has the FDA ever approved any nonspecific amplification method using random hexamer primers that didn't incorporate a target step?
MR. LIPSEY: Object to the form, lack of foundation.
A Not to my knowledge.
Q (By Mr. Bowen) Has the FDA to the best of your knowledge ever approved any assay that uses random hexamer primers?
MR. LIPSEY: Same objection.
A I'm not sure, but I believe that some of the assays based on RTPCR in which a template is first converted from RNA to DNA may use random hexamer primers.

sequences in the sample, i.e., the ratio of target to extraneous sequence is vastly increased." Closed quote.
A Okay.
Q Do you have an understanding of the word vastly when the article was published?
A I would say it's equivalent to substantially, substantially increased.
Q It's your understanding that methods of specific amplification increase the ratio of target to the other sequences in a sample; is that true?
A That's generally my opinion.
Q Nonspecific methods of amplification do not increase the relative proportion of the target and the other sequences in a sample; is that true?
MR. LIPSEY: Object to the form.
A It would depend on the nature of the nonspecific amplification technique.
Q I'd like you to look at what we'll mark as Exhibit 9, a document entitled declaration of Dr. David H. Persing in support of Vysis's opposition to Gen-Probe's motion for partial summary judgement. Is that your signature on Page 8 of Exhibit 9?
A Yes, it is.
Q I'd like to you look please of Page 3, Paragraph 8, line 24. At the end of line 24 a sentence begins quote, that

is because nonspecific amplification techniques amplify all the nucleic acid in a sample, both target and nontarget nucleic acid. End of quote.
A Yes.
Q That statement was true when you signed your declaration?
A Yes, I would agree with that statement.
Q And the next sentence states, quote, specific amplification techniques in contrast are intended to amplify only the target nucleic acid. Do you see that?
A Yes.
Q That was true when you signed your declaration?
A Yes.
Q And that's a difference between nonspecific and specific techniques, isn't it?
MR. LIPSEY: Object to the form.
A It's a difference in intent. It's not always a difference in outcome.
Q (By Mr. Bowen) Without the use of target capture prior to amplification, is nonspecific amplification a viable technique for detecting nucleic acids in samples?
MR. LIPSEY: Object to form, lack of foundation.
A Yes, I would say it would be a powerful method if the input material from a clinical specimen is enriched for

A Yes, it is in the context of the declaration, yes.
Q Do you understand here in the last sentence that you're communicating to the Court your belief that without a target capture step, nonspecific amplification can't be used in an diagnostic assay?
MR. LIPSEY: Object to the form.
The document speaks for itself.
A It does, and I think I wouldn't want to go beyond my declaration, the fact that the document spoke to the use of a -- to applying to clinical specimens for which there was a mixture of target and nontarget nucleic acids and for which nonspecific amplification methods would not be useful. And the specific example I just gave you where nonspecific amplification are equivalent to specific amplifications in their diagnostic utility only pertains to certain types of specimens in which there is natural enrichment for the target sequence, or natural enrichment by virtue of biological amplification of the material prior to analysis. So in a context of this declaration, it is a correct statement.
Q Specific amplification makes more copies of the needle in the haystack; is that true?
A Yes.
Q Nonspecific amplification makes copies of everything, both the needle and the haystack is that true?

A Specific amplification makes copies of the haystack as well, but the proportion is lower of haystack to needle.
Q Specific amplification increases the relative proportion of the needle in the haystack; is that true?
A I would say that's generally true.
Q Nonspecific amplification does not increase the relative proportion of the needle in the haystack generally. That's true; right?
A I think that's generally true.
Q Nonspecific amplification does not increase the amount of a particular sequence relative to all other nucleic acids in the sample; is that true?
A I think that's generally true.
Q Would you agree that when employed by one skilled in the art, methods of sequence specific amplification are extremely specific as compared with amplification using random hexamer primers?
MR. LIPSEY: Object to the form.
A I can't really comment on that because it would depend on the nature of the input target material, how pure the target was.
Q (By Mr. Bowen) If the target input was a mixture of nucleic acids in a human clinical sample, is it true that specific amplification methods are extremely specific as compared with random hexamer primer

publication?
A I did, yeah.
Q Had you had any experience with the Gen-Probe amplified tuberculosis assay as of 1997?
A No.
Q Were you aware that as of 1997 Gen-Probe had obtained FDA approval for mycobacterium tuberculosis assay?
A Yes.
Q And did you have an understanding that was an assay that used TMA amplification?
A That was my understanding.
Q And was it your understanding that that assay did not have a target capture step?
A I wasn't aware of the details of the assay at that time.
Q Is it your understanding today that that assay does not have a target capture step?
A I haven't used the assay so I can't -- can't speak to that.
Q So you don't know whether Gen-Probe has obtained FDA approval for TMA assays that don't include a target capture step?
A I believe that they have, but I don't -- I can't speak specifically to this instance.
Q Do you know what the clinical specificity of those assays is?

trying to get to your punch line.
A It will take me some time to go through this just to make sure I'm not --
Q (By Mr. Bowen) Let's talk about Example 5.
A Okay. All right.
Q Do you see that in the first paragraph of Example 5 it says, "in this example, both nonspecific replication of target DNA and transcription of that DNA are used to amplify?
A Yes.
Q Do you agree that this example describes nonspecific replication of target DNA and transcription of that DNA?
MR. LIPSEY: May I hear the question again, please?
(Question on Page ^ , Lines ^ through ^ , read by the reporter.)

MR. LIPSEY: Object to the form.
A Yeah, I really can't -- can't comment there. I'm not sure what the -- what the question is and what the --
Q (By Mr. Bowen) The question is, do you agree with the statement there in the first sentence of Example 5 that the example describes the use of nonspecific replication of target DNA and transcription of that DNA?

MR. LIPSEY: Object to the form.
A I think it does describe the use of oligohexamer primers which would be able to initiate replication nonspecifically, but it also contains a specific mention of sequence specific primer extension. So, you know, I don't know, I can't really comment beyond that except to say it seems to comprise elements of both.
Q (By Mr. Bowen) Do you see in the second paragraph of Example 5 there's a reference to Figure 5?
A Okay.
Q Would you look at Figure 5, which is at the front of the packet, please?
A Okay. Mm-hm.
Q Figure 5 describes the use of capture probe as a primer; is that your understanding?
MR. LIPSEY: Object to the form.
A (Witness reviews document.) Yes, I think in general terms it does describe use of a capture technique or sequence enrichment.
Q I'd like you to look please at Column 31 of the patent. Oops. I think I just did that wrong. I did. I'm sorry. Column 15. In Column 15, the left-hand column starting about Line 56, do you see that it says, "In Step 3 of Figures 4, 5 and 6 the isolated target is non-specifiably" -- I think that should probably be

nonspecifically -- "amplified to form a multitude of amplification products"?
A Okay. That's -- I agree that's what it -- that's what it reads.
Q And do you agree that figure -- that in Figure 5 the isolated target is nonspecifically amplified?
A Well, it's confusing because Example 5 does -- recites Figure 5, does specify the double-stranded DNA being used -- being captured specifically with a probe, and then the synthesis can start from the capture probe. So in that sense the initial steps of the amplification process are indeed specific. So it seems that there is a -- sort of a disconnect between the Example 5 and what's in Figure 5 and also what's in the content on the passage that you just read.
Q You said that the initial steps of the amplification process are specific if the capture probe is used as primer. Is the overall process described in Example 5 if the capture probe is used as a primer, specific amplification?
A I can't really comment on that. I think it comprises elements of specificity and of nonspecificity as do many amplification techniques.
Q I'd like you to look at what we will mark as Exhibit 14, which is an excerpt from the deposition of Jonathon

constitute amplification?
A I can't really say without seeing the Vary patent. I would just again say that the initial primer extension process is the initiating step in the amplification process and it may be it may require several rounds of primer extension initiation in a linear fashion before the amplification process kicks in to gear efficiently. Now, if -- that's all I really can say, is that the primary extension I think is critical step -- sequence specific primer extension is a critical step in initiating amplification. In fact, I say right here, "For example, amplification of nucleic acids by the polymerase chain reaction follows primer extension with separation of the double-stranded primer extension product into single-stranded polynucleotides and repeating the process steps."
So basically I again there point out that the primer extension is the initiating event within the amplification reaction.
Q Considering Example 5 and the use of the capture probe as the point to begin synthesis, is it your understanding that the replicated DNA resulting from that process would be nonspecific in size?
A Could be.
Q Is it your understanding --